DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

9/6088

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

WARNING LETTER

August 7, 2001

via Federal Express

MQSA Facility ID: 123430
Inspection ID: 1234300010

FDA Reference #: 2951759

Dawn Gonzales, Director Diagnostic Operations
Radiological Associates of Sacramento, Inc. - Roseville
1500 Expo Parkway
Sacramento, CA 95661

Dear Dawn Gonzales:

We are writing to you because on July 12, 2001, your facility, located at 1130 Conroy Lane, # 100, Roseville, CA, was inspected by a representative of the State of CA, acting in behalf of the Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following level 1 findings at your facility:

- Level 1: Phantom QC records were missing for at least 4 weeks for unit 2, [redacted], room Mammo [redacted] Room
- Level 1: Phantom QC records were missing for at least 4 weeks for unit 4, [redacted] room Mammo [redacted] Room

The specific problems noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. These problems are identified as Level 1, because they identify a failure to meet a significant MQSA requirement.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a serious

violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA Standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

In addition, your response should address the Level 2 findings that were listed on the inspection report provided to you at the close of the inspection. These Level 2 findings are:

- Level 2: The phantom image score (using an FDA- approved mammography phantom) is at least 2 but is less than 3 speck groups for unit 2, [redacted] room Mammo [redacted] Room

- Level 2: The measured fog density is equal to 0.1 for darkroom Main at site Radiological Associates of Sacramento, Inc. - Roseville

- Level 2: Failed to produce documents verifying that the interpreting physician [redacted] (0 CME's in 36 months) met the continuing education requirement of having taught or completed at least 15 category 1 continuing medical education units in mammography in 36 months

- Level 2: Corrective action before further exams, for a failing image score, or a phantom background optical density, or density difference outside the allowable regulatory limits, was not documented for unit 4, [redacted], room Mammo [redacted] Room

- Level 2: Corrective action before further exams, for a failing image score, or a phantom background optical density, or density difference outside the allowable regulatory limits, was not documented for unit 2, [redacted] room Mammo [redacted] Room

We acknowledge receipt of Denise Plank's, Site Supervisor, letter dated July 23, 2001. Ms. Plank's response appears to adequately address the Level 1 and Level 2 findings discussed above. Your corrective actions will be verified during the next inspection.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O.

Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Russell A. Campbell, Compliance Officer at (510) 337-6861.

Sincerely yours,

for Dennis K. Linsley
District Director